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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,519	01/03/2002	Catherine A. McCall	SC-1-C2	6037
7590 02/10/2004				
Heska Corporation 1613 Prospect Parkway Fort Collins, CO 80525			EXAMINER YANG, NELSON C	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/038,519	MCCALL ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 12-19, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-11 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 5-8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/09/02, 5/6/02</u>  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, 20-22, drawn to a device for the rapid detection of allergen-specific IgE, classified in class 435, subclass 287.2.
  - II. Claims 12-19, 23,24, drawn to a method for the rapid detection of the presence of allergen-specific IgE, classified in class 435, subclass 7.1.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the apparatus of group I can be used as a filter, while the method of group II can be performed by electrochemical arrays.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for others, restriction for examination purposes as indicated is proper.
5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations

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of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

6. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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7. During a telephone conversation with Richard Stern on January 28, 2004 a provisional election was made with traverse to prosecute the invention of group I, claims 1-11, 20-22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-19, 23, 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Information Disclosure Statement***

9. The information disclosure statement filed December 9, 2002 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Specification***

10. The attempt to incorporate subject matter into this application by reference to applications US 5,073,484 and US 5,654,162 is improper because they do not describe a

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lateral flow device. Rather, the applications describe devices with generally vertical liquid flow path.

### ***Claim Objections***

11. Claims 5-8 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5-8 limit the preamble of claim 1, which has no patentable weight. As a result, claims 5-8 fail to further limit the subject matter of claim 1, and no patentable weight is given to the claims.

### ***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

14. Claim 4 recites the limitation that the mixture of allergens is deposited on an area of the porous member separate from the sample receiving area. However, it is unclear from the claims and the specification how applicant would ensure contact of the sample with the mixture of allergens in order to allow for detection of allergen specific-IgE.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 1-4, 9-11, 20-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Frank et al [US 5,945,294] in view of Chu [US 5,541,059].

Frank et al teach a porous member (a substrate in which the substrate materials include paper and nitrocellulose and shapes include a microtiter dish well and a lateral flow apparatus) (column 10, line 65 – column 11, line 13) with a mixture of allergens (flea saliva allergens), in order to detect the presence of IgE (column 2, lines 30-42), and a control (purified dog IgE) (column 20, example 8). Frank et al also teach a support member (absorbant member) in direct contact with the first member (column 13, lines 50-53). Frank fails to specifically teach that the mixture of allergens and the control are spotted on the porous member. Chu, however, teaches a device comprising a first member comprising a porous member having a sample receiving area, where the porous member is spotted with antigens and a control spot (figs. 1-7, column 3, lines 35-59), and a support member in direct contact with the first member (column 3, lines 9-16). Chu teaches that the device allows a person of ordinary skill in the art to see if an error occurred in performing the immunoassay procedure, or if one or more reagents are defective, or if the sample is diluted beyond the sensitivity of the system to allow for

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detection. Therefore it would have been obvious to spot the porous member with a mixture of allergens, as taught by Chu, in the device of Frank et al, in order to allow for the detection of IgE, while also allowing for the detection of defective reagents or errors in performing the immunoassay procedure.

17. With respect to claim 2, in the device taught by Chu, antigens are deposited on one spot of the porous member (fig. 1, column 3, lines 35-59).

18. With respect to claim 3, in the device taught by Chu, antigens are deposited on multiple spots of the porous member (fig. 2, column 3, lines 35-59).

19. With respect to claim 4, Frank et al teach a sample receiving area where the mixture of allergens is deposited on an area (capture zone) of the porous member separate from the sample receiving area (column 13, lines 20-53).

20. With respect to claims 5-8, the claims add further limitations to a sample, which is not part of the device. Therefore no patentable weight is given the claims.

21. With respect to claim 9, Chu teaches a device further comprising an absorbent member in capillary communication with the porous first member, where absorbent member induces flow of liquid through the first member (capillary action) (column 3, lines 9-16 and column 4, lines 38-47).

22. With respect to claim 10, Frank et al teach a control spot containing purified IgE (purified dog IgE) (figs. 5, 6 and column 20, examples 8 and 9).

23. With respect to claim 11, Frank et al teach that the mixture of allergens comprise flea saliva proteins (column 2, lines 39-42).

24. With respect to claim 20, Chu teaches a kit comprising a device and ancillary reagents (first and second labeled antibodies) (column 6, lines 48-55).



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25. With respect to claim 21, Frank et al teach a lateral flow device (column 15, lines 6-18).

26. With respect to claim 22, Chu teaches a flow through device (column 3, lines 9-16).

### ***Conclusion***

27. No claims are allowed.

28. The following references are also cited as art of interest: Lawton et al [US 6,504,013], Frank et al [US 6,060,326], and Miller et al [US 5,418,136].

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Nelson Yang

Patent Examiner

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BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
2/6/04